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**STATE OF DELAWARE
BOARD OF PHARMACY**

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, April 29, 2014 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	June 18, 2014

MEMBERS PRESENT

Joli Martini, R.Ph., PharmD, Professional Member, President
Kimberly Robbins, R.Ph, Professional Member, Vice President
Sandra Zaragoza, R.Ph, Professional Member
Susan Esposito, R.Ph, Professional Member
Tejal Patel, R.Ph, PharmD, Professional Member
Bonnie Wallner, R.Ph, Professional Member
Kenneth Sellers, Public Member
Jay Galloway, Public Member
David W. Dryden, R.Ph., J.D., Executive Secretary

MEMBERS ABSENT

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

David Mangler, Director, Division of Professional Regulation
Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III

ALSO PRESENT

Scott Setzepfandt
Alfred M Gathura
Tami Brown
Deron Johnson
Tim Lyder
Don Dolst
Stephen Marmaras
Karl S Schumann
Amy Dempster
Candie Phipps
Jeffrey Robinson
Loredana Cromarty
Jaime Frink

Janis Levit
Sandy Robinson
Michelle McCreary
Deborah Hamilton
Rebecca Byrd
Julie Miro Wenger
Carl Tepper
Kevin Musto

CALL TO ORDER

Ms. Martini called the meeting to order at 9:31 a.m.

REVIEW OF MINUTES

A motion was made by Ms. Zaragoza, seconded by Ms. Patel, to table the meeting minutes for April 16, 2014. The motion unanimously carried.

PRESIDENT'S REPORT

Ms. Martini had no report.

UNFINISHED BUSINESS

Complaint Status

13-03-11 – Assigned to Hearing Officer
13-09-11 – Assigned to Hearing Officer
13-12-11 – Forwarded to Office of Attorney General
13-19-11 – Forwarded to Office of Attorney General
13-09-12 – Assigned
13-01-13 – Forwarded to Office of Attorney General
13-02-13 – Assigned
13-03-13 – Assigned
13-04-13 – Forwarded to Office of Attorney General
13-05-13 – Assigned
13-06-13 – Forwarded to Office of Attorney General
13-07-13 – Assigned
13-08-13 – Assigned
13-09-13 – Assigned
13-11-13 – Forwarded to Office of Attorney General
13-13-13 – Forwarded to Office of Attorney General
13-14-13 – Assigned
13-15-13 – Assigned
13-16-13 – Assigned
13-17-13 – Assigned
13-18-13 – Assigned
13-19-13 – Assigned
13-20-13 – Assigned
13-21-13 – Assigned
13-22-13 – Assigned
13-23-13 – Assigned
13-24-13 – Assigned

Board Discussion Substitution 1 SB118

Ms. Martini opens the discussion to any public member whom wished to address the Board regarding SB118. Members of the public presented their views to the board. Mr. Jeffrey Robinson of Sandoz Pharmaceuticals; provided information in support of SB118. Mr. Scott Setzepfandt of Genentech; provided information in support

of SB118. Mr. Steven Marmaras of Global Healthy Living Foundation; provided information in support of SB118. Ms. Tami Brown of Merck; provided information in support of SB118. Mr. Karl Schumann R.Ph. and President of Pharmacom; provided information in support of SB118. Ms. Juli Miro Wenger, Delaware State Chain Drug Association; provided information in opposition of SB118. Mr. Tim Lyder of Lilly Pharmaceuticals; provided information in support of Substitution 1 SB118. Ms. Rebecca Byrd of Express Scripts; provided information in opposition of SB118. Mr. Deron Johnson of AMGEN; provided information in support of SB118.

After the opposing and supporting views were presented to the board by the public, discussion by the board ensued. Ms. Esposito expressed concerns in the hospital setting regarding the required use of formularies and the costs associated with bio-similar prescribed once released from the hospital. She expressed concerns regarding insurance carriers and the costs of drugs that are not covered being passed on to the patients after the fact. Mr. Sellers expressed concern with line 29 which requires the reporting of “all” biosimilar substitutions when the prescription issued by the physician authorizes substitution. Therefore this bill is not necessary. Ms. Patel agreed with Mr. Sellers concerns. Ms. Patel expressed concerns related to substitutions for the veterinary population that would also increase reporting for the pharmacist. Ms. Martini expressed concerns regarding the additional reporting will prevent the pharmacist from delivering true patient care due to time constraints of the additional reporting. Physicians have busy practices and are not easily available to pharmacists. Ms. Robbins expressed concerns regarding the additional reporting that will be placed on Pharmacists if this bill passes. Ms. Kelly advised the board on the process required to attend committee meetings and hearings on behalf of the board. Mr. Sellers expressed his concern that the board was previously included in discussions with SB118 prior to being presented to legislation in 2013. The Substitution 1 SB118 bill currently discussed was not presented to the board for review therefore appearing that the bill was trying to be presented without the consideration of the board. A motion was made by Mr. Sellers, seconded by Ms. Esposito to oppose Substitution 1 SB118. The motion unanimously carried.

A motion was made by Ms. Esposito, seconded by Mr. Sellers to delegate Ms. Martini spokesperson on behalf of the board regarding legislature surrounding Substitution 1 SB118. The motion unanimously carried.

Review of Letter of Support “Harold Rogers Grant”

Ms. Martini read the letter of support drafted by Samantha Nettesheim. A motion was made by Ms. Robbins, seconded by Ms. Esposito to approve the letter. The motion unanimously carried.

Signing of Consent Agreement – Neil Bavitz

Ms. Kelly presented the board with the signature page of the consent agreement that was approved during the March 19, 2014 meeting for the board members signatures. The agreement was passed to the board members for signature.

Review of Applications for Final Denial

None

Re-Review of Tabled Applications

None

NEW BUSINESS

Pharmacist and Intern Licensure Approval Ratifications

A motion was made by Ms. Robbins, seconded by Ms. Patel to table the ratification of the Pharmacist and Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A motion was made by Ms. Robbins, seconded by Ms. Patel to table the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A motion was made by Ms. Robbins, seconded by Ms. Patel to table the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A motion was made by Ms. Robbins, seconded by Ms. Patel to table the ratification of the Medical Gas Dispensers applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A motion was made by Ms. Robbins, seconded by Ms. Patel to table the ratification of the Retail Pharmacy applications. The motion unanimously carried.

Pharmacist-In-Charge Interviews

Ms. Robbins conducted an interview with Alfred M Gathura, he is employed by Rite-Aid Camden, DE.

Consultant Pharmacist Interviews

Ms. Robbins conducted an interview with Carl Tepper, he is employed by Atlantic Shores Nursing Facility Millsboro, DE.

Board Review of Consent Agreement

None

Review of Applications by DAG

Pharmacy board DAG Eileen Kelly provided guidance on the following disciplinary actions for applications received followed by the board ruling:

Facility: Leiters Compounding – Non Resident Pharmacy, a motion was made by Ms. Robbins, seconded by Ms. Wallner, to approve the application. The motion unanimously carried.

Facility: Vital Rx, Inc.. – Non Resident Pharmacy, a motion was made by Ms. Wallner, seconded by Ms. Robbins, to approve the application. The motion unanimously carried.

Review of Draft Technician Licensure Statute

Ms. Robbins expressed that the committee has been working for the past year developing this legislation. Ms. Kelly provided "Draft" legislation for the board to review. Ms. Robbins explained the two types of licensure for Technicians; Certified Pharmacy Technician (PTCB Certified) and Non-Certified Pharmacy Technician. The Non-Certified Pharmacy Technician will have a nonrenewable expiration of 24 months after licensure. The board discussed the draft and requested that the board review further and discuss at the next meeting.

Discussion of Statutory provisions pertaining to Discipline

Ms. Kelly expressed some concerns regarding adding statutory language to assist with disciplining out of state pharmacies. The current legislation does not provide the necessary statute to support the prosecuting attorney with discipline if necessary. The current Pharmacy disciplinary statute is not currently in line with division practices. Ms. Kelly will put a draft statute change together for review during the next scheduled meeting.

COMMITTEE REPORTS

Legislative – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel and David Dryden

Mr. Mangler wanted to follow up on the presentations made earlier regarding SB118 and Substitute 1 SB118 and express that he on behalf of the division is neutral regarding this legislation.

Continuing Education – Joli Martini, Bonnie Wallner, and David Dryden:

No Report

Consumer Affairs – Ken Sellers and Jay Galloway:

No Report

Professional Liaisons – Kim Robbins and Sandra Zaragoza:
No Report

Controlled Substance Liaisons – Joli Martini, Jay Galloway and David Dryden:
Mr. Dryden stated that the nation drug disposal was held on April 26th and was a big success again. The NASCA grant is also in the works and we are awaiting the official approval of that grant. Draft regulation for the PMP was presented to the committee for review during its meeting on April 23, 2014.

COMMITTEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee – Sandy Robinson, Howard Simon, Alicia Kluger, Brenda Pavlic, Sandra Zaragoza, Hooshang Shanehsaz, Calvin Freedman and David Dryden:
No Report

Pharmacy Technician Licensure Committee – Howard Simon, Kim Robbins, Tejal Patel, Kevin Musto, Maryanne Holzapfel, Anne Pyle, Sandy Esposito and David Dryden:
Draft Legislation provided for discussion earlier in the agenda.

Collaborative Care Committee – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Howard Simon, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:
Ms. Miro Wenger reported that the committee has not met since the last pharmacy meeting. The main focus has been on Substitute1 SB118 and has taken away the ability to focus on this current issue. The committee is hopeful to present draft legislation for review at its next board meeting in June.

BOARD CORRESPONDENCE

None

EXECUTIVE SECRETARY AND INSPECTION REPORT - David Dryden, Samantha Nettesheim

Mr. Dryden reported that the new inspector Michelle McCreary is in continued training, conducting, and completing inspections.

NEWSLETTER UPDATES

May newsletter will be available soon. Email alert will notify pharmacists when it's available online.

OTHER BUSINESS BEFORE THE BOARD

None

PUBLIC COMMENT

Mr. Musto provided a reminder of the Golf Scramble to benefit pharmacy scholarship funds.

NEXT SCHEDULED MEETING

The next meeting is scheduled for June 18, 2014 at 9:30 Am., Conference Room A 2nd floor.

ADJOURNMENT

There being no other business before the board. A motion to adjourn was made by Ms. Robbins, seconded by Ms. Patel. The motion unanimously carried at 11:14 am.

Respectfully submitted,



Christine Mast
Administrative Specialist III